DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 9, 2014

Innovative Trauma Care, Inc.
Richard Waite
Sr. Director of Quality Assurance/ Regulatory Affairs
3463 Magic Dr., Suite 120
San Antonio, Texas 78229

Re: K140805
Trade/Device Name: iTClamp50
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: August 15, 2014
Received: August 29, 2014

Dear Mr. Waite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140805

Device Name
iTClamp50

Indications for Use *(Describe)*
The iTClamp50 is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla, inguinal areas, scalp, and neck.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the iTClamp™50 is provided below.

Device Common Name:	Vascular Clamp
Device Proprietary Name:	iTClamp™50
Submitter:	Innovative Trauma Care, Inc. 3463 Magic Dr., Suite 120 San Antonio, TX 78229
Contact:	Richard Waite Sr. Director of Quality Assurance/ Regulatory Affairs, 3463 Magic Dr., Suite 120 San Antonio, TX 78229 Office: 210-582-5850 ext. 1932 FAX: 210-582-5851 Cell: 214-662-9277 rwaite@innovativetraumacare.com
Date Prepared:	February 17, 2014
Classification Regulation:	870.4450
Panel:	Cardiovascular
Product Code:	DXC
Predicate Device	K132651 – iTClamp™50

Indication for Use
The iTClamp™50 is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla, inguinal areas, scalp, and neck.

The purpose of this 510(k) is to modify the already cleared indication for use to include use of the device on severe bleeding areas of the neck.

Device Description
The iTClamp™50 is a clamp device that quickly controls critical bleeding by closing the skin to create a temporary, contained hematoma until surgical repair. The iTClamp50 is a self-locking surgical clamp with suture needles that penetrate the skin to evert the skin edges (similar to sutures or staples) between pressure bars of the device and anchor it to the skin to

reduce slippage and leakage. Pressure is evenly distributed across the bars, which seal the skin over a wound. An adjustable locking mechanism increases or decreases pressure across the wound to achieve a fluid tight seal.

The iTClamp controls bleeding by sealing the skin closed to apply direct pressure to the cut edges of the skin and create a temporary pool of blood (hematoma) under pressure. This permits formation of a stable clot until the patient can receive medical care and/or surgical repair.

The device is provided sterile and is for single use.

The iTClamp consists of the following components:

1) Suture needles
2) Plastic shell
3) Locking mechanism
4) Lock release mechanism

Biocompatibility Testing

Additional Biocompatibility Testing is not necessary to support the modified indication for use. Physical composition of the product, sterilization and packaging has not changed in anyway; therefore, biocompatibility testing provided in the previous 510(k) (K132651) is applicable to support this 510(k).

Performance Testing - Bench

Additional bench performance testing is not necessary. The physical composition of the product, packaging and sterilization has not changed in any way. Therefore, the bench testing provided in the previous 510(k) (K132651) is applicable to this 510(k).

Innovative Trauma Care has performed cadaver testing to demonstrate substantial equivalence of the iTClamp50 for the new proposed indication for use on neck wounds. In addition, a second cadaver study was generated which compared the performance of the iTClamp50 and standard of care, i.e. tamponade by direct manual pressure and balloon catheter inflation in a wound. The results of the Cadaver Studies demonstrate that the device is suitable for use on the neck and is substantially equivalent to the previous 510(k) K132651.

A user assessment was performed utilizing 15 trained first responders (fire fighters) to ensure the Directions for Use (DFU) were appropriate to support the clearance of K132651. The assessment utilized a bleeding arm simulator model. The simulator model uses a pulsing pump motor to delivery pulses of simulated blood (water) through a wound in the arm with pressure of 80-90 mmHg. The environmental conditions they were exposed to were: Normal conditions, cold hands, non-dominant hand, and dominant hands, low light, strobe lights, in a shower and underwater using a skin pad, fatigued hand (one hand exhausted), with fire gloves

on. These were completed using both wet hands (to simulate blood they were wetted with glycerol/water solution) and dry hands wearing vinyl exam gloves (except when wearing firefighting gloves and gear). The primary assessment was external leakage of water from the wound while the pump continued to run. Additionally, user needle sticks were evaluated. The outcome of the user assessment identified that the training based upon the DFU provided sufficient information for all participants to successfully apply and remove the device; the occurrence of needle stick was <1% in 270 device applications (Environmental use of the iTClamp™ 50 in a group of firefighters, Mckee, J., Mckee, I., Gao, H., Frost, G., Kirkpatrick, A. W.) The DFU content for the application and removal of the device has not changed and the technique remains the same within the scope of the expanded Indications for Use, therefore no additional user testing was conducted to support the temporary control of severe bleeding in neck wounds.

Performance Testing – Animal

Not applicable. Animal Performance Testing is not necessary to establish the substantial equivalence of the device.

Performance Testing – Clinical Study

Case studies were captured to support product performance for the cleared indications. For expansion of the indication to include temporary control of severe bleeding in the neck, data from unsolicited case studies of OUS and off-label use provided supportive data on the device performance for treatment of neck wounds.

Substantial Equivalence

The iTClamp50 is the same device that was previously cleared in K132651 to provide temporary bleeding control to wounds in the extremities, axilla, inguinal areas, and scalp until medical and/or surgical repair can be obtained. The iTClamp™ used for the new indication on the neck raises no new or different types of effectiveness questions because direct pressure is the standard of care for bleeding wounds to the neck.

The available performance data support use of the iTClamp50 for neck wounds. The iTClamp50, therefore, is substantially equivalent to the already cleared iTClamp50 classified under 870.4450.

	Subject Device	**Predicate Device**
510(k) Number	TBD	K132651
Classification / Procode	870.4450 / DXC	870.4450 / DXC
Device Name	iTClamp™50	iTClamp™50
Manufacturer	Innovative Trauma Care, Inc.	Innovative Trauma Care, Inc.

	Subject Device	Predicate Device
Indication for Use	The iTClamp50 is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla, inguinal areas, scalp and neck**.**	The iTClamp50 is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla, inguinal areas and scalp**.**
Device Design	iTClamp50 is a self-locking surgical clamp with suture needles that penetrate the skin to evert the skin edges between pressure bars of the device and anchor it to the skin to reduce slippage and leakage. Pressure is evenly distributed across the bars, which seal the skin over a wound. An adjustable locking mechanism increases or decreases pressure across the wound to achieve a fluid tight seal or wound closure as desired.	iTClamp50 is a self-locking surgical clamp with suture needles that penetrate the skin to evert the skin edges between pressure bars of the device and anchor it to the skin to reduce slippage and leakage. Pressure is evenly distributed across the bars, which seal the skin over a wound. An adjustable locking mechanism increases or decreases pressure across the wound to achieve a fluid tight seal or wound closure as desired.
Device Operation	Application of pressure by applying clamp to temporarily seal wound site	Application of pressure by applying clamp to temporarily seal wound site
Picture